REMARKS

In the office action, claims 1-4 and 15-18 have been rejected under 35 U.S.C. §112, and claims 1-4 and 15-18 have been rejected under 35 U.S.C. §103(a). In response, claims 1-4 and 15-18 have been cancelled, and new claims 19-28 have been added. Accordingly, claims 19-28 are pending in the application.

In response to the above rejections, Applicants respectfully submit the following remarks.

The Invention

The invention is for a real time (e.g. results in less than thirty minutes) insulin test system that has at least one reservoir having monoclonal anti-insulin or anti-C peptide capture antibodies coated onto the surface, and at least one photomultiplier detector. The reservoir receives a sample, a wash solution, and labeled monoclonal anti-insulin or anti-C peptide antibodies that allow photometrical detection.

Support for New Claims

19. cancelled claim 1; (insulin, e.g., page 6, line 5);

20. cancelled claim 2;

21. cancelled claim 3;

22. cancelled claim 4;

23. cancelled claim 15;

24. cancelled claim 16;

25. cancelled claim 17;

26. cancelled claim 18;

27. page 6, lines 6-8;

28. page 5, line 6.

Rejections under 35 U.S.C. §112

Claim 1 has been rejected under §112, second paragraph, as being indefinite with respect to the term "solidified" and the phrase "capable of."

In the office action, the term "solidified" has been rejected as vague. In response, claim 1 has been cancelled and new claim 19 has been added which corresponds to cancelled claim 1. New claim 19 recites "anti-insulin or anti-C peptide antibodies are coated onto a surface of the reservoir." Support for the amendment can be found on page 6, line 19 of the application.

Hence, the rejection of claim 1 with respect to the term "solidified" has been rendered moot.

In the office action, the Examiner has rejected claim 1 for reciting the phrase "capable of" with respect to the reservoir's ability to receive a sample, a wash solution, and labeled monoclonal anti-insulin or anti-C peptide antibodies.

During a telephone discussion with Examiner Counts on May 5, 2003, the rejection of claim 1 for reciting "capable of" was discussed. Examiner Counts explained that the phrase "capable of" is not a positive recitation.

At the Examiner's suggestion, new claim 19 recites "the reservoir receives a sample, a wash solution, ..." Applicants extend their gratitude to Examiner Counts for taking the time to discuss this rejection.

Accordingly, the rejection under §112 of the phrase "capable of," in claim 1, has been rendered moot.

Rejections under 35 U.S.C. §103

Claims 1 and 4 have been rejected under §103(a) as being unpatentable over Nanakome et al., "Immunoreactive Proinsulin Detected By Enzyme Linked Immunosorbent Assay," Biomedical Research 18(5) 389-393 (1997) in view of U.S. Patent No. 4,626,684 to Landa et al.

Nanakome discloses an assay for measuring pro-insulin that utilizes a microplate reader. In fact, in the Abstract, Nanakome explains that the disclosed assay failed to detect both insulin and C-peptide. The Examiner recognizes that Nanakome fails to disclose a photomultiplier detector.

However, the Examiner contends that because Landa discloses using a photomultiplier detector for florescence immunoassay, it would have been obvious to one of ordinary skill in the art to substitute the photomultiplier detector of Landa for the microplate reader of Nanakome, and arrive at the claimed invention. Applicants respectfully disagree.

As explained above, the present invention is for a real time test system that measures insulin levels. By "real time" it is meant that the test system provides a result in a short period of time. For example, results become available in less than thirty (30) minutes. See page 6, lines 6-10.

Nanakome discloses an assay for measuring pro-insulin (a precursor of insulin), and expressly teaches away from using such an assay to measure insulin. See above and Abstract of nanakome.

Importantly, the assay disclosed by Nanakome requires a lengthy incubation period, for example, three days. See page 389, column 2. Nanakome does not disclose a "real time" test system for measuring insulin levels. Landa merely discloses a fluorescence analyzer.

In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art references, when combined, must teach or suggest all of the claim limitations. See MPEP §2142. Applicants' have emphasized above the importance of the test system being "real time" and measuring "insulin" levels.

Upon combining the teachings of Nanakome and Landa, all of the claim limitations are neither taught or suggested. Therefore, based on the foregoing discussion, Applicants' claimed invention cannot be obvious over Nanakome in view of Landa. Accordingly, Applicants respectfully request reconsideration of the above §103 rejection based on Nanakome in view of Landa.

Claim 2 has been rejected under §103 as being unpatentable over Nanakome and Landa in view of U.S. Patent No. 4,517,289 to Milford et al.

The Examiner recognizes that neither Nanakome or Landa disclose labeled monoclonal anti-insulin antibodies in dried form. However, the Examiner contends that because Milford discloses the use of lyophilized monoclonal antibodies, it would have been obvious to one or ordinary skill to incorporate the lyophilized antibodies of Milford in the method of Nanakome and arrive at the claimed invention.

As discussed above, Nanakome discloses an assay for measuring pro-insulin that requires a lengthy incubation period, for example, three days. Landa merely discloses a fluorescence analyzer.

Milford discloses a hybridoma cell line that produces antibodies that react with human HLA antigens. Milford discloses a kit that contains such antibodies in stable form, e.g. lyophilized.

As already explained, the present invention is for a test system that measures insulin levels and produces results in a short period of time, i.e. real time. As recited in claim 2, the claimed test system utilizes monoclonal anti-insulin or anti-C peptide antibodies that can be in a reservoir in dried form.

In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art references, when combined, must teach or suggest all of the claim limitations. See MPEP §2142. Applicants' have emphasized above the importance of the test system being "real time" and measuring "insulin" levels.

Upon combining the teachings of Nanakome, Landa, and Milford, all of the claim limitations are neither taught or suggested. Therefore, based on the foregoing discussion, Applicants' claimed invention cannot be obvious over Nanakome and Landa, in view of

Milford. Accordingly, Applicants respectfully request reconsideration of the above §103 rejection based on Nanakome and Landa, in view of Milford.

Claim 3 has been rejected under §103 as being unpatentable over Nanakome and Landa in view of U.S. Patent No. 4,946,958 to Campbell et al.

The Examiner recognizes that neither Nanakome or Landa disclose a chemiluminescent label. However, the Examiner contends that because Campbell discloses a chemiluminescent label linked to a monoclonal antibody, it would have been obvious to one or ordinary skill to incorporate the chemiluminescent label of Campbell in the method of Nanakome and arrive at the claimed invention.

As discussed above, Nanakome discloses an assay for measuring pro-insulin that requires a lengthy incubation period, for example, three days. Landa merely discloses a fluorescence analyzer.

Campbell discloses a compound that is useful as a chemiluminescent label and that can be linked to a monoclonal antibody.

The present invention is for a test system that measures insulin levels and produces results in a short period of time, i.e. real time. As recited in claim 3, the claimed test system

utilizes monoclonal anti-insulin or anti-C peptide antibodies that can be labeled with a chemiluminescent label.

In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art references, when combined, must teach or suggest all of the claim limitations. See MPEP §2142. Applicants' have emphasized above the importance of the test system being "real time" and measuring "insulin" levels.

Upon combining the teachings of Nanakome, Landa., and Campbell, all of the claim limitations are neither taught or suggested. Therefore, based on the foregoing discussion, Applicants' claimed invention cannot be obvious over Nanakome and Landa, in view of Campbell. Accordingly, Applicants respectfully request reconsideration of the above §103 rejection based on Nanakome and Landa, in view of Campbell.

In the office action, claim 15-18 have been rejected under §103 as being unpatentable over Nanakome and Landa, in view of Schulz et al., Band 68 Heft 3, pp.309-318 (1976) (abstract only in English).

Claim 16 has been rejected further in view of Milford, and claim 17 has been rejected further in view of Campbell.

The examiner recognizes that none of Nanakome, Landa, Milford or Campbell disclose or suggest obtaining a sample by a probe arranged to be introduced in the *Vena porta*.

However, the Examiner contends that because Schulz discloses obtaining a sample by insertion of a catheter in the *Vena porta*, it would have been obvious to one of ordinary skill in the art to obtain a sample as taught by Schulz for use in the method of Nanakome.

As discussed above, Nanakome discloses an assay for measuring pro-insulin that requires a lengthy incubation period, for example, three days. Landa merely discloses a fluorescence analyzer.

Campbell discloses a compound that is useful as a chemiluminescent label and that can be linked to a monoclonal antibody.

Milford discloses a hybridoma cell line that produces antibodies that react with human HLA antigens. Milford discloses a kit that contains such antibodies in stable form, e.g. lyophilized.

Schulz discloses a comparison of portal and peripheral blood samples with respect to blood glucose, insulin, proinsulin and glucagons levels.

The present invention is for a test system that measures insulin levels and produces results in a short period of time, i.e. real time. As recited in claims 15-18, the claimed test system utilizes a sample that is obtained by a probe arranged to be introduced into the *Vena splenica* or *Vena* porta.

In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art references, when combined, must teach or suggest all of the claim limitations. See MPEP §2142. Applicants' have emphasized above the importance of the test system being "real time" and measuring "insulin" levels.

Upon combining the teachings of Nanakome, Landa., and Milford or Campbell, in view of Schulz, all of the claim limitations are neither taught or suggested. Therefore, based on the foregoing discussion, Applicants' claimed invention cannot be obvious over Nanakome and Landa, and Milford or Campbell, in view of Schulz. Accordingly, Applicants respectfully request reconsideration of the above §103 rejection based on Nanakome and Landa, and Milford or Campbell, in view of Schulz.

In light of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, he is invited to contact

the undersigned at his convenience.

Respectfully submitted,

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